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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q67685

Shingo KATO, et al.

Appln. No.: 10/009,897

Group Art Unit: 1634

Confirmation No.: 4572

Examiner: Jeanine Anne Goldberg

Filed: December 14, 2001

For: METHOD FOR DETERMINING HIV-1 SUBTYPE

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office (European Search Report EP 00 93 7241), except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant is filing

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/009,897

concurrently herewith a Statement Under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.


Respectfully submitted,

SUGHRUE MION, PLLC  
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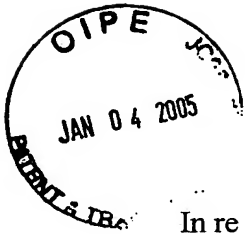
WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

  
Mark L. Hayman  
Registration No. 51,793

Date: January 4, 2005



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**STATEMENT UNDER 37 C.F.R. § 1.97(e)**

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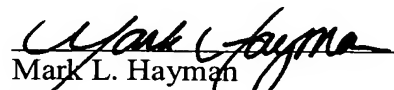
Sir:

The undersigned hereby states, upon information and belief:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

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Substitute for Form 1449 A &amp; B/PTO

Complete if Known

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

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Application Number	10/009,897
Confirmation Number	4572
Filing Date	December 14, 2001
First Named Inventor	Shingo KATO
Art Unit	1634
Examiner Name	Jeanine Anne Goldberg
Attorney Docket Number	Q67685

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US			
		US			
		US			
		US			
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		US			
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		US			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Pieniazek D. et al., "Identification of mixed HIV-1/HIV-2 infections in Brazil by polymerase chain reaction," AIDS, Vol. 5, No. 11, 1991, pages 1293-1299	n/a
		Susan Engelbrecht et al., "Detection of South Africa human immunodeficiency virus type 1 subtypes by polymerase chain reaction: evaluation of difference primer pairs and conditions," Journal of Virological Methods, Vol. 55, No. 3, 1995 pages 391-400	n/a
		Maurizio Zazzi et al., "Nested Polymerase Chain Reaction for Detection of Human Immunodeficiency Virus Type 1 DNA in Clinical Specimens," Journal of Medical Virology, Vol. 38, No. 3, 1992 pages 172-174	n/a
		F. Coutlee et al., "The polymerase chain reaction: a new tool for the understanding and diagnosis of HIV-1 infection at the molecular level," Molecular and Cellular Probes, Vol. 5, No. 4, 1991, pages 241-259.	n/a

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.